



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Everolimus (tablets 2.5 mg/5 mg, dispersible tablets 2 mg/3 mg)

June 5, 2018

Non-proprietary name

Everolimus (tablets 2.5 mg/5 mg, dispersible tablets 2 mg/3 mg)

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Impaired wound healing:

Impaired wound healing may occur or lead to wound infection, incisional hernia, wound dehiscence, or other complications. If any abnormalities are observed, appropriate measures, such as discontinuation of administration, should be taken.